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Fred H. Burbank

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Doherty IP Law Group LLC  
37 Belvidere Ave  
Washington, NJ 07882

EXAMINER

HOUSTON, ELIZABETH

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## DETAILED ACTION

A telephone interview with Mike Dougherty on 11/19/08 led to the determination that the refusal to enter the amended claims filed 09/29/08 was incorrect. As a result of this action, the claims are being entered. It has further been determined that the indication of allowable subject matter was in error and is being withdrawn based a new ground of rejection in view of newly applied prior art.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6, 47, 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Hasson (US 5,562,680).

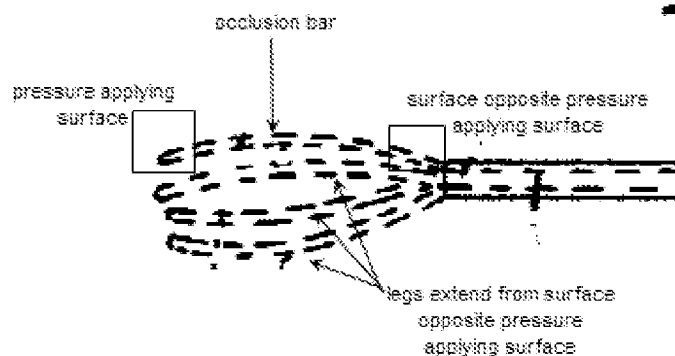
3. Hasson discloses an intravaginal device *capable of* occluding a female patient's uterine arteries with an unsymmetrical anatomy to treat a uterine disorder, comprising: a first occluding member having a first elongated shaft (14), a first operative proximal shaft section (88,90) configured to extend out of the patient during treatment, which has a first distal shaft section (18) with a first pressure applying occluding element (82) secured to the first distal shaft section (in that all the elements of the device are secured to each other), and a first mechanism/extending actuator (86, 92) to distally extend at

Art Unit: 3731

least part of the first pressure applying occluding element from a first position closer to the first operative proximal shaft section to a second position further away from the first operative proximal shaft section and for moving the first pressure applying surface distally away from the distal end of the first elongated shaft (Fig. 7; C6:L6-18); and a second occluding member (16) having a second elongated shaft, a second operative proximal shaft section configured to extend out of the patient during treatment and a second distal shaft section with a second pressure applying occluding element secured to the second distal shaft section; and a connection (46) between the first and second occluding members which is configured to adjust spacing between the first and second pressure applying occluding elements (C5: L13-20) to press the pressure applying occluding elements against the patient's vaginal wall to occlude underlying uterine arteries. Regarding claim 2 the second occluding member has a second mechanism to distally extend at least part of the second pressure applying occluding element from a first position closer to the second operative proximal shaft section to a second position further away from the second operative proximal shaft section (see Fig. 1 and above elements with respect to first occluding member). Regarding claim 3 the connection between the first and second occluding members is a pivotal connection (Fig. 5 and 6; C5: L17). Regarding claim 4, each of the proximal shaft sections of the occluding members includes a finger engaging grip (C6:L10-15). Regarding claim 5, at least part of the first pressure applying occluding element is configured for positional adjustment in-line with the first distal shaft section (Fig. 7). Regarding claim 6, at least part of the first pressure applying occluding element is configured for rotation within a plane at or

Art Unit: 3731

near the first distal shaft section (via pivot at connection (46) in Fig. 6). Regarding claims 47 and 48 the first pressure applying element includes an occlusion bar with a pressure applying surface and a pair of legs which extend from a surface opposite the pressure applying surface (see below).



4. Claims 3234, 37, 40 rejected under 35 U.S.C. 102(b) as being anticipated by Hasson (US 4,944,741).

5. Regarding claim 32: Hasson discloses an intravaginal device *capable of* occluding a female patient's uterine arteries with an unsymmetrical anatomy to treat a uterine disorder, comprising: a first occluding member having a first elongated shaft (16), a first operative proximal shaft section configured to extend out of the patient during treatment (see below), a first distal shaft section (32) with a first pressure applying occluding element (28) secured to the first distal shaft section, and a first mechanism (one of spring 60) to distally extend at least part of the first pressure applying occluding element from a first position closer to the first operative proximal

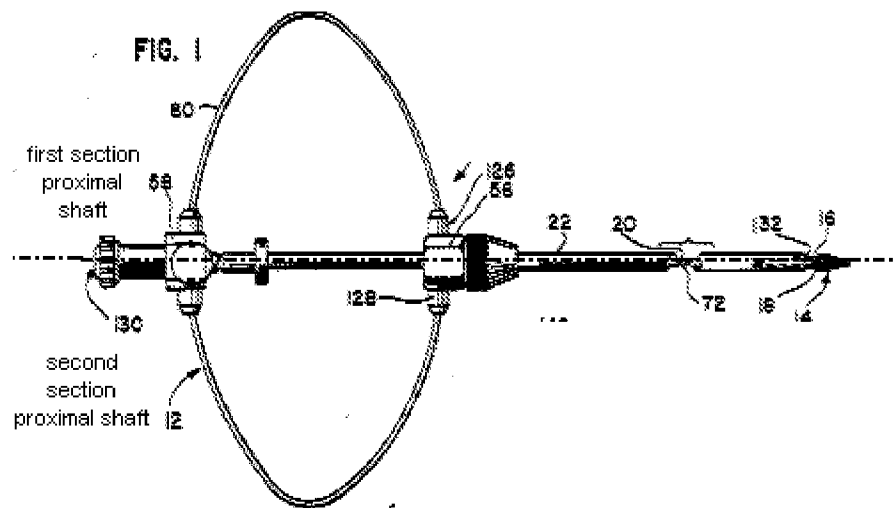
Art Unit: 3731

shaft section to a second position further away from the first operative proximal shaft section (C4:L45-65); and a second occluding member having a second elongated shaft (18), a second operative proximal shaft section configured to extend out of the patient during treatment (see below) and a second distal shaft section (34) with a second pressure applying occluding element (30) secured to the second distal shaft section, wherein the second occluding member has a second mechanism (other of spring 60) to distally extend at least part of the second pressure applying occluding element from a first position closer to the second operative proximal shaft section to a second position further away from the second operative proximal shaft section; and a connection (at core 72) between the first and second occluding members which is configured to adjust spacing the first and second pressure applying occluding elements (core 72 is pushed distally, pushing occluding members distally, thereby adjusting spacing (C4:L45-65)) so that it is *capable of* pressing the pressure applying occluding elements against the patient's vaginal wall to occlude underlying uterine arteries, wherein the first pressure applying occluding element is pivotally connected (at pin 40) to the distal shaft section of the first occluding member and the first occluding member includes a third mechanism (112, C5:L46-63) for selectively rotating the first pressure applying occluding element relative to the distal shaft section of the first occluding member.

6. Regarding claim 34: Hasson discloses an intravaginal device *capable of* occluding uterine arteries comprising: a first occluding member having a first elongated shaft (16) with a proximal end and a distal end, a first occluding element (28) secured to the distal end (32) of the first elongated shaft, the first occluding element having a first

Art Unit: 3731

pressure applying surface (36) at a distal end thereof, and a first extending actuator (one of spring 60) coupled with the first occluding element for selectively moving the first pressure applying surface distally away from the distal end of the first elongated shaft (C4:L45-65), wherein the first occluding element is pivotally connected ( 44) with the distal end of the first elongated shaft and the device further comprises a rotating actuator (112) coupled with the first occluding element for selectively rotating the first pressure applying surface through a range of angles relative to the first elongated shaft (C5:L46-63); and a second occluding member having a second elongated shaft (18) with a proximal end and a distal end (34), a second occluding element (30) secured to the distal end of the second elongated shaft, the second occluding element having a second pressure applying surface (38) at a distal end thereof; and the first and second occluding members being coupled together (via rod 72) for selectively adjusting spacing between the first and second pressure applying surfaces (core 72 is pushed distally, pushing occluding members distally, thereby adjusting spacing (C4:L45-65)). As to claim 37: The second occluding member further comprises a second extending actuator (other of spring 60) coupled with the second occluding element for selectively moving the second pressure applying surface distally away from the proximal end of the second elongated shaft.



### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hasson (US 5,562,680) in view of Malecki (US 6,368,340).

9. Hasson discloses the invention substantially as claimed as stated above including a mechanism that extends the occlusion element distally away from the distal shaft section, but does not disclose that the mechanism for extending the occlusion element is effected by fluid under pressure.

10. Malecki discloses a clamp assembly that utilizes a hydraulic actuator for moving the occlusion element (C 20: L28-53). Malecki states that the use of a hydraulic system



is an advantage because it does not take up much room in a trocar sleeve and enhances visualization (C 18: L 55-60).

It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a hydraulic system in place of the biasing springs into the invention of Hasson. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Furthermore, the hydraulic system is an enhancement over the mechanism used by Hasson for the reasons taught by Malecki and stated above.

11. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasson (US 5,562,680).

12. Schifano fails to particularly disclose that the occluding member is displaced a distance of up to about one inch of between 0.25 to 0.8 inch from the distal shaft section. However, it would have been obvious to displace the occluding member a varied distance of up to about one inch or between 0.25 to 0.8 inch from the distal shaft section in order to make the device of a sufficient size to be used to occlude uterine arteries. See *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Art Unit: 3731

13. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasson (US 5,562,680) in view of Hossack et al (US 6,045,508).

14. Hasson discloses the invention substantially as claimed above but fails to disclose a blood flow sensor. However, Hossack teaches a Doppler crystal mounted in the surface of a device meant to be placed within the body (col. 3, lines 35-37 and col. 4, lines 49-51). Therefore it would have been obvious to add the Doppler crystal of Hossack to the occlusion device of Hasson, in order to monitor blood flow to ensure that too much pressure is not being applied. Additionally, it would have been obvious to position the Doppler crystal so that it has a direction of view away from the pressure applying surface of the occluding element, so that the blood flow in the artery adjacent to the device can be measured.

15. Claims 36 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasson (US 4,944,741) in view of Hossack et al (US 6,045,508).

16. Hasson discloses the invention substantially as claimed above but fails to disclose a blood flow sensor. However, Hossack teaches a Doppler crystal mounted in the surface of a device meant to be placed within the body (col. 3, lines 35-37 and col. 4, lines 49-51). Therefore it would have been obvious to add the Doppler crystal of Hossack to the occlusion device of Hasson, in order to monitor blood flow to ensure that too much pressure is not being applied. Additionally, it would have been obvious to position the Doppler crystal so that it has a direction of view away from the pressure

Art Unit: 3731

applying surface of the occluding element, so that the blood flow in the artery adjacent to the device can be measured.

***Allowable Subject Matter***

17. Claims 12, 33, 38 and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

18. Claims 41, 43-46 are allowed.

***Response to Arguments***

19. Applicant's arguments filed 04/07/09 have been fully considered but they are not persuasive. While, Hasson '680 (and Hasson'714 for that matter) does not disclose that the device is used for occluding arteries, examiner asserts that the device would be capable of applying pressure to the uterine arteries such that they would be capable of occluding the arteries. Applicants state that the Hasson '680 does not teach a second mechanism to distally extend part of the second pressure applying occluding element. However, as seen in Fig. 1, even though elements are not labeled, there are clearly two independent shafts each having its own spring mechanism for extending the distal ends distally.

***Conclusion***

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

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/E. H./

Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/

Supervisory Patent Examiner, Art Unit 3731

6/22/09